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Reza Yacoob
Director, Intellectual Property
Sanofi Pasteur Ltd.
1755 Steeles Ave.
Ontario, Toronto, Canada

In Re: Patent Term Extension
Application for
U.S. Patent No. 5,877,298

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JULY 12 2012
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# NOTICE OF DETERMINATION ON ELIGIBILITY

An application for extension of the patent term of U.S. Patent No. 5,877,298 (the '298 patent) under 35 U.S.C. § 156 was filed in the United States Patent and Trademark Office on August 15, 2008. The application was filed by Sanofi Pasteur Limited, the successor-in-interest of the patent owner of record, Connaught Laboratories. Extension is sought based upon the premarket review under § 351 of the Public Health Services Act (PHSA) of a human biological product known by the tradename PENTACEL® having the active ingredients diphtheria toxoid, tetanus toxoid, pertussis toxoid, filamentus hemaglutinin, fimbriae 2 & 3, pertactin, poliovirus 1, poliovirus 2, poliovirus 3, and PRP-T. PENTACEL® was approved for commercial use and sale by the Food and Drug Administration (FDA) on June 20, 2008.

In a letter dated August 19, 2009 from FDA to the USPTO (FDA letter), the FDA indicated that PENTACEL® had been subject to a regulatory review period under BLA 125145 in accordance with section 351 of the PHSA and confirmed that BLA 125145 did not represent the first permitted commercial marketing or use of each of the active ingredients in PENTACEL®.

A single request for reconsideration of this FINAL DETERMINATION OF INELIGIBILITY may be made if filed by the applicant within TWO MONTHS of the mailing date of this letter. The period for response may be extended pursuant to 37 C.F.R. 1.136. See 37 C.F.R. 1.750. A failure to respond to this letter will result in the application papers being placed into the patent file with no further action taken on the application for patent term extension.

A determination has been made that U.S. Patent No. 5,877,298 is **NOT** eligible for patent term extension under 35 U.S.C. § 156 based upon the regulatory review period of PENTACEL®.

FDA official records indicate that each of the active ingredients comprising PENTACEL® were previously approved for commercial marketing or use prior to the approval of PENTACEL®. In the FDA letter, FDA stated:

> A review of the Food and Drug Administration's official records indicates that this product was subject to a regulatory review period before its commercial marketing or use, as required under 35 U.S.C. § 156(a)(4). However, our records also indicate that it does not represent the first permitted commercial marketing or use of the product, as defined under 35 U.S.C. § 156(f)(1). The active ingredients in Pentacel have each been approved previously for commercial marketing or use in sanofi Pasteur's products Daptacel (DTaP), Poliovax (IPV) and ActHib (Hib).

Under 35 U.S.C. § 156(a) a term of a patent which claims a product shall be extended if, *inter alia*, the product has been subject to a regulatory review period before its commercial marketing or use. In addition, under § 156(a)(5)(A):

> the permission for the commercial marketing or use of the product . . . is the first permitted commercial marketing or use of the product under the provision of law under which such regulatory review period occurred; (Emphasis added)

Thus, the determination of eligibility of U.S. Patent No. 5,877,298 turns on the provisions in § 156(a)(5)(A) that the permission for the commercial marketing or use is the first permitted commercial marketing or use of the product. The term "product" is defined in 35 U.S.C. § 156(f) as follows:

> (f) For purposes of this section:
> (1) The term "product" means:
> (A) A drug product . . .
> (2) The term "drug product" means the active ingredient of -
> (A) A new drug, antibiotic drug, or human biological product . . . .including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient. (Emphasis added.)

By the explicit terms of section 156(f)(2), the term "product" as it relates to a drug product, in particular a human biological product, means the active ingredient of the human biological product. See In re Fisons Pharmaceuticals Limited, 231 USPQ 305 (Comm'r Pats. 1986); aff'd, Fisons plc v. Quigg, 8 USPQ2d 1491 (DDC 1988); aff'd, 10 USPQ2d 1869 (Fed. Cir. 1988) (holding that the term "product" as used in § 156(f) refers to the active ingredient); Glaxo Operations UK Ltd. v. Quigg, 13 USPQ 1628 (Fed. Cir. 1990) (holding that the term "product" as used in § 156(f) refers to the active ingredient).

In addressing compliance with section 156 (a)(5)(A) for a drug product including two active ingredients, the court in Arnold P'ship v. Dudas, 362 F.3d 1338, 1341 (Fed. Cir. 2004) held that a composition comprised of multiple active ingredients is eligible for patent term extension only if at least one of the active ingredients complies with the first commercial marketing requirement of § 156(a)(5)(A). Thus, for regulatory review of a drug product with more than one active ingredient to give rise to eligibility for extension of a patent claiming the drug product, permission to commercially market and use the product must be the first permitted commercial marketing or use of at least one of the active ingredients. The active ingredients in the approved product PENTACEL® are diphtheria toxoid, tetanus toxoid, pertussis toxoid, filamentus hemaglutinin, fimbriae 2 & 3, pertactin, poliovirus 1, poliovirus 2, poliovirus 3, and PRP-T. As noted in the FDA letter, the active ingredients of PENTACEL® had each been approved for commercial marketing and use prior to the approval of PENTACEL®. Furthermore, the prior approval of each of the active ingredients diphtheria toxoid, tetanus toxoid, pertussis toxoid, filamentus hemaglutinin, fimbriae 2 & 3, pertactin, poliovirus 1, poliovirus 2, poliovirus 3, and

PRP-T by the FDA occurred under section 351 of the PHSA, the same provision of law under which regulatory review of the product PENTACEL® occurred. Thus, since none of the active ingredients, diphtheria toxoid, tetanus toxoid, pertussis toxoid, filamentus hemaglutinin, fimbriae 2 & 3, pertactin, poliovirus 1, poliovirus 2, poliovirus 3, or PRP-T, constitute the first permitted commercial marketing or use, the '298 patent does not appear to be eligible for extension based on the regulatory review of PENTACEL®.

Applying the definition of "product" provided in § 156(f) to the extension requirement of § 156(a)(5)(A), Applicant's product PENTACEL® does not qualify as the first permitted marketing or use of any of the active ingredients. Since the approval of PENTACEL® was not the first permitted marketing or use of at least one of the active ingredients thereof, diphtheria toxoid, tetanus toxoid, pertussis toxoid, filamentus hemaglutinin, fimbriae 2 & 3, pertactin, poliovirus 1, poliovirus 2, poliovirus 3, or PRP-T, the patent is not eligible for patent term extension based upon the regulatory review of PENTACEL®.

Because the approval of PENTACEL® fails to comply with the requirement of section 156(a)(5)(A), the application for patent term extension of the '298 patent under 35 U.S.C. 156(d)(1) is **dismissed**.

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.

Mary C. Till
Senior Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

RE: PENTACEL®
Docket No.: FDA-2009-E-022